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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/523,538

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Kenji Sunagawa

KUP-6

7543

20808

7590

08/06/2008

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EXAMINER

KAHELIN, MICHAEL WILLIAM

ART UNIT

PAPER NUMBER

3762

MAIL DATE

DELIVERY MODE

08/06/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/523,538	<b>Applicant(s)</b> SUNAGAWA, KENJI	
	<b>Examiner</b> MICHAEL KAHRELIN	<b>Art Unit</b> 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 10-18 is/are pending in the application.
- 4a) Of the above claim(s) 14-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                        |                                                                   |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20080709(1); 20080709(2)</u> .                                | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Claims 14-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 2/18/2008.
2. Applicant's election without traverse of claims 10-13 in the reply filed on 2/18/2008 is acknowledged.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:  

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 10-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. In regards to claims 10-13, the term and/or is vague. Examiner is interpreting the term as "or."
6. In regards to claims 11 and 13, the "control signal to be sent outside" is inferentially included. It is suggested to recite the step of "sends the control signal outside."

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rasor et al. (US 3,943,936, hereinafter "Rasor") in view of Heller (US 6,294,281, hereinafter "Heller").

9. In regards to claim 10, Rasor discloses the essential features of the claimed invention, including a pacemaker capable of implantation with the tip of a catheter and requiring no chest incision (Figs. 5A-5C and 9) having a control unit (30), a heart stimulating means (output of 30), an electrocardiograph information detecting means ("trigger input" and col. 11, lines 8-13), and a fuel cell power unit (col. 3, lines 19-21), wherein the control unit outputs the control signal based on the ECG information (col. 11, lines 8-13). Rasor does not disclose that the fuel cell is a biological fuel cell that extracts electrons from oxidative reactions of biological fuels comprising an anode and cathode, wherein the anode is coated with immobilized oxidative enzymes and the fuel cell uses blood or body fluid as an electrolyte solution and utilizes biological fuels and oxygen in the blood or body fluid. Heller teaches a biological fuel cell for use with implantable devices (col. 2, lines 60-67) that extracts electrons from oxidative reactions of biological fuels comprising an anode and cathode, wherein the anode is coated with immobilized oxidative enzymes (col. 2, lines 3-9) and the fuel cell uses blood or body fluid as an electrolyte solution and utilizes biological fuels and oxygen in the blood or body fluid (col. 2, lines 44-58) to provide the predictable results of powering an implantable device without the need for replacing or recharging batteries. Therefore, it

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would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Rasor's invention by providing a biological fuel cell that extracts electrons from oxidative reactions of biological fuels comprising an anode and cathode, wherein the anode is coated with immobilized oxidative enzymes and the fuel cell uses blood or body fluid as an electrolyte solution and utilizes biological fuels and oxygen in the blood or body fluid to provide the predictable results of powering an implantable device without the need for replacing or recharging batteries.

**10.** In regards to claims 11-13, Rasor's modified invention discloses the essential features of the claimed invention except for a transmitting/receiving means to modulate and send/receive ECG information and control signals that are output/input into the control unit. It is well known in the art to provide implantable pacemakers, such as the one taught by Rasor with transmitting/receiving means to modulate and send/receive ECG information and control signals that are output/input into the control unit to provide the predictable results of modifying device function with changing patient conditions and acquiring patient diagnostic information from inside the body. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify Rasor's invention by providing transmitting/receiving means to modulate and send/receive ECG information and control signals that are output/input into the control unit to provide the predictable results of modifying device function with changing patient conditions and acquiring patient diagnostic information from inside the body.

***Conclusion***

**11.** The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Fujii et al. (US 5,411,535) is one of many teachings of a two-way telemetry system for miniature implantable devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL KAHELIN whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/  
Primary Examiner, Art Unit 3762

/Michael Kahelin/  
Examiner, Art Unit 3762

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